

Remarks

The above-identified application has been carefully reviewed in light of the Examiner's office action mailed on February 2, 2006.

Applicant hereby petitions for a one-month extension of time to Respond to the office action, thereby extending the deadline for response up to and including June 2, 2006. The requisite fee for filing for a one-month extension of time is filed herewith.

Claim 44 has been amended to correct a typographical error. Specifically, in line 3 of claim 44, the phrase "the strip of rotating" have been changed to "the step of rotating". No new matter is being added by this amendment.

The Examiner has objected to claim 39 based on informalities and states that correction is required. Specifically, the Examiner states that claim 39 appears to claim the same subject matter as that in claim 33. Applicant respectfully disagrees

Claim 33 and claim 39 define different embodiments of the invention. Specifically, claim 33 defines the method of claim 30 *wherein the cannula and rotational element are sized and positioned* so that the rotating step is effective to create suction effective in drawing the material from the breast into the open distal tip of the cannula. Claim 39 defines the method of claim 30 *wherein the rotational element is cooperatively engaged with the cannula and structured* so that the step of rotating is effective to create suction effective in drawing the material from the breast into the cannula. These two claims are different and distinct, one from the other, and do not claim the

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same subject matter. For this reason, applicant requests that the objection to claim 39 be withdrawn.

The Examiner has objected to claim 44 due to the phrase "strip of rotating" in line 3. Applicant has corrected this error by substituting "step of rotating" for the incorrect phrase "strip of rotating". Applicant submits that this amendment overcomes the Examiner's objection to claim 44.

The Examiner has rejected claims 30-33 and 36-45 under 35 U.S.C. 102(e) as being anticipated by Fox. The Examiner has further rejected claims 34 and 35 under 35 U.S.C. 103(a) as being unpatentable over Fox as applied to claim 30 and further in view of Shiber. Applicant traverses each of these rejections as it pertains to the present claims.

The present claims provide methods of removing material from a breast of a human or animal. The methods remove material from a breast less invasively and/or with reduced risk to the patient relative to many prior art devices and procedures.

Independent claim 30 defines a method of removing material from a breast which comprises the steps of placing into a breast of a human or an animal a cannula having an open, distal tip and a rotational element disposed at least partially in the cannula, and rotating the rotational element relative to the cannula, thereby at least assisting in drawing a material from the breast into the open distal tip of the cannula.

Fox does not disclose, teach or suggest the present invention. For example, Fox does not disclose, teach or even suggest methods of removing material from a breast including the step of placing into a breast a cannula having an open, distal tip and a rotational element disposed at least partially in the cannula, as recited in the present claims. Further, Fox does

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not disclose, teach or even suggest the step of rotating the rotational element relative to the cannula, thereby at least assisting in drawing a material from the breast into the open distal tip of the cannula, as recited in the present claims.

Applicant submits that Fox does not even suggest placing any part of the device in a breast of a human or animal. To the contrary, the tip of the Fox device is structured to be placed on the outer surface of a solid bone, to serve as a "brace" against the bone while the rotating element longitudinally moves into the bone. This aspect of the Fox instrument is shown, for example, in Fig. 3a and 3b and is described throughout the description. For example, in column 11, lines 17-19, Fox explains, "The tip (10, 100, 103) contacts a cutting surface without penetrating into it, and serves as a cutting tool guide of brace and bearing" [emphasis added]. Fox does not suggest anything regarding drawing material from a breast of a human or animal into the disclosed instrument.

In view of the above, applicant submits that the present claims 30-33 and 36-45 are not anticipated by and are patentable over Fox under 35 U.S.C. 102(e).

Applicant further submits that Shiber does not supply the deficiencies apparent in Fox and, therefore, the combination of Fox in view of Shiber does not render the present claims unpatentable.

The Examiner states that Shiber discloses an atherectomy system and method which discloses a cannula having an outer diameter no larger than about 5mm and a cannula no larger than about 2mm, and that "[i]t would be obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Fox to include a cannula diameter of no more than 5mm or 2mm, as per the teachings of Shiber, since it

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would provide a less invasive medical device for obtaining a tissue sample". Applicant respectfully disagrees.

As explained hereinabove, Fox provides a device with a tip structured to be braced against a bone surface and a rotating element for channeling into the bone while the tip remains braced against the outer surface of the bone.

Shiber discloses an atherectomy catheter "useful for treating small arteries in the heart or brain... which requires a ...catheter having a diameter as small as 1 mm" (Shiber, column 7, lines 11-15). Neither Fox nor Shiber suggests anything regarding removing tissue from a breast of a human or animal, let alone the methods as recited in the present claims.

In view of the fact that Fox specifically teaches a tip structured not to penetrate bone, there would be no motivation for a person of ordinary skill in the art to combine the teachings of Fox with the atherectomy-related teachings of Shiber for any purpose, let alone for the purpose of making obvious the methods of removing material from the breast of a human or animal, as recited in the present claims.

Applicant submits that the substantial, even dramatic, differences between a blood vessel and a bone of a body are such that one of ordinary skill in the art would not even attempt to combine the blood vessel-related teachings of Shiber and the deficient bone-related teachings of Fox for any purpose. Moreover, one of ordinary skill in the art would not even attempt to combine the two different teachings of Fox and Shiber for the purpose of providing the methods for removing material from a breast of a human or animal, as recited in the present claims.

In view of the above, applicant submits that the present

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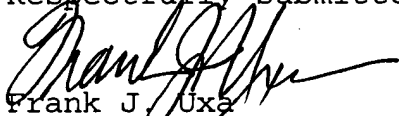
claims 34 and 35 are unobvious from and patentable over Fox in view of Shiber under 35 U.S.C. 103(a).

Further, each of the present dependent claims is separately patentable over the prior art. For example, none of the prior art, taken singly or in any combination, disclose, teach or even suggest the presently claimed methods including the additional feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

In conclusion, applicant has shown that the present claims are not anticipated by Fox under 35 U.S.C. 102(e), and are unobvious from and patentable over Fox in view of Shiber under 35 U.S.C. 103(a). Therefore, applicant submits that the present claims, that is claims 30-45, are allowable and respectfully requests the Examiner to pass the above-identified application to issuance at an early date.

Should any matters remain unresolved, applicant respectfully requests the Examiner to contact applicant's attorney at the telephone number given below.

Respectfully submitted,



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